GUIDANCE FOR FDA STAFF

Compliance Policy Guide

Evaluation and Processing of Post Donation Information Reports

U.S. Department of Health and Human Services
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COMPLIANCE POLICY GUIDE
CHAPTER - 2
SUB CHAPTER - 230

Sec. 230.140 Evaluation and Processing Post Donation Information Reports

INTRODUCTION:

This compliance guidance document is an update to the Compliance Policy Guides Manual (August 1996). It is a new CPG and will be included in the next printing of the manual. It is based on guidance provided to industry representing the agency's current thinking on the evaluation and processing of post donation information reports. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations. It is intended for FDA personnel and is available electronically to the public.

BACKGROUND:

The Center for Biologics Evaluation and Research (CBER) issued a memorandum to blood establishments on December 10, 1993, that provided guidance concerning process control procedures that should be established, implemented, and maintained for the receipt, evaluation, investigation, and follow-up of post donation information reports. Post donation information includes information provided by the donor or other source that is received or obtained following a donation, or at a subsequent donation during the health history screening process, that relates to the suitability of the donor or of the blood or blood component.

Under the provisions of 21 CFR 606.100, written standard operating procedures (SOPs) shall be maintained for all steps to be followed related to the collection, processing, testing, handling, storage and distribution of blood and blood components. These SOPs must include, but are not limited to, criteria for donor suitability, investigating adverse reactions, and thorough investigation and follow up of any unexplained discrepancy or failure of a lot or unit to meet specifications. 21 CFR 606.160 requires the maintenance of records concurrent with the performance of each significant step in the collection, processing, compatibility testing, storage and distribution of each unit of blood and blood components. These records are to be as detailed as necessary to provide a complete history of the work performed. Records also shall be maintained, when applicable, of donor information, donor adverse reaction complaints, investigation and followup, and errors and accidents.

Under 21 CFR 211.100, written procedures for production and process controls for drug products must, be established and followed. 21 CFR 211.192 includes requirements for thorough investigation of any unexplained discrepancy or failure of a batch or its components to meet any specification. 21 CFR 211.198 requires that written procedures and records for handling complaints shall be established and followed.

POLICY:

Blood establishments, therefore, must have written

procedures in place and follow them to handle and follow up on the receipt of post donation information. These SOPs should include procedures for the following:

(1) receipt and documentation of post donation information reports that identify the source of the information;

(2) prompt medical evaluation by a physician or other qualified person following established criteria, to ensure that potential risks are consistently assessed and investigated for all donations potentially affected;

(3) timely investigation of the reports to determine whether an error or accident in manufacturing occurred and whether the safety, purity, or potency (hereafter, "quality") of blood and blood components may have been affected;

(4) quarantine, at the establishment, of all products still under its control until the firm determines whether the products are suitable for distribution;

(5) appropriate consignee notification regarding the disposition of all affected products (see below);

(6) assessment of the donor's suitability to serve as a donor in the future; and

(7) obtaining more detailed information and further clarification, in a confidential manner, when a donor reports that his or her blood should not be used.

In September 1998, FDA provided further guidance to industry, indicating that blood establishments should have SOPs that include consignee notification relative to the receipt of certain post donation information concerning anti-HCV. In addition, current regulations require consignee notification for purposes of HIV lookback and blood establishments must have SOPs for such notification. See 21 CFR 610.46 and 606.100(b)(19). Blood establishments also may establish SOPs that include consignee notification in additional circumstances, e.g., in written procedures for handling post donation information. Blood establishments should follow these SOPs when such procedures have been established. As good manufacturing practices and other regulatory requirements change, all firms must revise their SOPs to reflect these changes.

If post donation information suggests that product quality may be compromised, but more detailed information or clarification cannot be obtained and thus a medical evaluation cannot be made, blood establishments should have SOPs for determining whether 1) retrieval of in-date, non-transfused, or unused products is appropriate, 2) products under the control of the establishment should be quarantined, and 3) consignees should be notified regarding the disposition of all affected products (in-date, used/transfused, and expired), including those intended for transfusion and those intended for further manufacturing use.

REGULATORY ACTION GUIDANCE:

Districts should consider enforcement action if a blood establishment fails to establish, implement, and/or follow written SOPs that include receipt, evaluation, investigation, and follow-up of post donation information reports. However, good manufacturing practices and other regulatory requirements may vary, based on the type of post donation information received. Before citing a firm for failure to establish or follow SOPs regarding consignee notification after receipt of post donation information, Districts should identify the good manufacturing practices and other regulatory requirements applicable to the situation under review. If there is any question about such applicable requirements, CBER should be contacted before making such a charge.

In addition, Districts also should consider enforcement action if the blood establishment fails to take effective corrective action in response to

procedural deficiencies that were identified through investigations of post donation information.

Citations for failure to establish and follow procedures for handling post-donation information or failure to take effective corrective action may be included in direct reference warning letters for GMP deficiencies, in accordance with the Regulatory Procedures Manual, Chapter 4, and the Compliance Program for inspections of blood facilities, or may be cited in other actions against the firm.

CBER, Office of Compliance and Biologics Quality (OCBQ), should be contacted if investigators have serious concerns regarding the firm's medical evaluation of post donation information it received. OCBQ will coordinate a health assessment with CBER's Office of Blood Research and Review, as appropriate.

Note: Policy related to the reporting of errors or accidents associated with the manufacture of blood and blood components is discussed separately. See memorandum issued to all registered blood establishments on March 20, 1991, "Responsibilities of Blood Establishments Related to Errors & Accidents in the Manufacture of Blood & Components."